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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/836,474 04/18/01 LEUNG S 845.27,700

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK NY 10112

EXAMINER

WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/836,474

Applicant(s)

LEUNG ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Receipt of preliminary amendment file 4-18-01 is acknowledged. Claims 1-17 and 31-47 have been canceled as requested. claims 18-30 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 18-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Recitation of "water-soluble ingredients" is indefinite. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "water-soluble ingredients" in claim 18 is used by the claim to mean "copper gluconate or sweeteners," while the accepted meaning is not limited to these ingredients.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 18-21, 24 and 28-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roreger et al (5,456,745; hereafter '745).

'745 discloses methods of making flexible, hydrophilic gel films comprising water-soluble film forming polymers that are substantially the same as those of the instant claims (abstract; C 2, L 32-55; C 3, L 61- C 4, L 29; C 7, L 59-60; C 11, L62- C 12, L 4; Examples, such as 23).

6. Claims 18, 24 and 28-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Horstmann et al (5,629,003; hereafter '003).

7. '003 discloses processes of making water soluble films that are the same as those of the instant claims (Abstract; C 3, L 56-61, 67; Examples).

8. Claims 18-19, 24 and 28-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Zerbe et al.

'430 discloses processes of making water soluble films that are the same as those of the instant claims (Abstract; C 2, L 31-64; C 3, L 32-40; Examples).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al (5,456,745; hereafter '745).

'745 teaches methods of making flexible, hydrophilic gel films comprising water-soluble film forming polymers that are substantially the same as those of the instant claims (abstract; C 2, L 32-55; C 3, L 61- C 4, L 29; C 7, L 59-60; C 11, L 62- C 12, L 4; Examples, such as 23). '745 does not teach drying the film to a moisture content between 3 and 8 percent. However, it would have been obvious to one skilled in the art at the time of the invention to dry the films to a moisture content of about this range, depending on the amount of flexibility desired and the types and amounts of auxiliaries added as '745 teaches that inclusion of moisturizers and water impart flexibility upon the gel film. '745 also does not specifically state cooling the aqueous solution/film-forming mixture subsequent to heating, however it would have been obvious to one skilled in the art at the time of the invention to allow the mixture to cool and continue the process of making at a later date for time constraint purposes and convenience. Furthermore, '745 does not teach formation of the polymer gel without heating. As the specification teaches that the gel may be formed with or without heating, this does not appear to be a critical aspect of the invention. Also, it is submitted that it would have been obvious to one skilled in the art at the time of the invention to omit heating the polymer/aqueous solution in the instance where the polymer dissolves, is soluble or becomes hydrated in the solution without heating to eliminate this step (MPEP 2144.04 II).

11. Claims 18, 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horstmann et al (5,629,003; hereafter '003).

'003 teaches processes of making water soluble films that are substantially the same as those of the instant claims (Abstract; C 3, L 56-61, 67; Examples). '003 does not teach that the total amount of the oils is at least about 5% or at least about 15% nor that the films have a moisture content of about 3 and 8%, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to include greater amounts of oils for greater oral hygiene purposes and to adjust the moisture content according to remove the solvents completely or almost completely from the film. '003 also does not teach the limitations of claim 25, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to omit heating the polymer/aqueous solution in the instance where the polymer dissolves, is soluble or becomes hydrated in the solution without heating to eliminate this step (MPEP 2144.04 II).

12. Claims 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (5,948,430; hereafter '430).

'430 teaches processes of making water soluble films that are substantially the same as those of the instant claims (Abstract; C 2, L 31-64; C 3, L 32-40; Examples). '430 does not teach that the total amount of the oils is at least about 5% or at least about 15% nor that the films have a moisture content of about 3 and 8%, however it is

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submitted that it would have been obvious to one skilled in the art at the time of the invention to include greater amounts of oils for greater oral hygiene purposes and to adjust the moisture content according to remove the solvents completely or almost completely from the film. '430 also does not teach the limitations of claim 25, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to omit heating the polymer/aqueous solution in the instance where the polymer dissolves, is soluble or becomes hydrated in the solution without heating to eliminate this step (MPEP 2144.04 II).

13. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al (5,456,745; hereafter '745) in view of Hijiya et al (4,562,020; hereafter '020).

'745 is relied upon for all that it teaches as stated previously. '745 does not teach the limitation of claim 30 where the water soluble polymer is pullulan.

'020 teaches strong, water soluble films comprising pullulan.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to substitute the water soluble polymers of '745 with pullulan for the strength properties of pullulan.

14. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horstmann et al (5,629,003; hereafter '003) in view of Hijiya et al (4,562,020; hereafter '020).

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'003 is relied upon for all that it teaches as stated previously. '003 does not teach the limitation of claim 30 where the water soluble polymer is pullulan.

'020 teaches strong, water soluble films comprising pullulan.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to substitute the water soluble polymers of '003 with pullulan for the strength properties of pullulan.

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (5,948,430; hereafter '430) in view of Hijiya et al (4,562,020; hereafter '020).

'430 is relied upon for all that it teaches as stated previously. '430 does not teach the limitation of claim 30 where the water soluble polymer is pullulan.

'020 teaches strong, water soluble films comprising pullulan.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to substitute the water soluble polymers of '430 with pullulan for the strength properties of pullulan.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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June 16, 2001